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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,590	06/01/2006	Arnold I Caplan	CWR-7781PCT/US	1634
68705 7550 01/05/2010 TAROLLI, SUNDHEIM, COVELL & TUMMINO, LLP 1300 EAST NINTH STREET			EXAMINER	
			POPA, ILEANA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/550,590 CAPLAN ET AL. Office Action Summary Examiner Art Unit ILEANA POPA 1633 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 September 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-4, 6, 8, 9, 11, 13-18, 20-26, 29, 32-39, 41,45-48,50,52,545-59,61-67,70,73-80,82,84-89.9697.99.101.103-105.107.109.110.112.114-119.121-127.130.133-140.142.143.145.147-149.151.153.154.156.158-163,165-171,174,177-184,186 and 188-191, is/are pending in the application. 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration. Claim(s) is/are allowed. 6) Claim(s) 1,2,4,6,8,9,11,13-15,26,29,39,41,45,47,48,50,52,54-56,67,70,80,82,85,190 and 191 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,16-18,20-25,32-38,46,57-59,61-67,73-79,84,86-89,97,91,01,103-105,107,109,110,112,114-119,121-127,130,133-140,142,143,145,147-149,151,153,154,156,158-163,165-171,177-184,186,188 and 189.

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DETAILED ACTION

1. Claims 5, 7, 10, 12, 19, 27, 28, 30, 31, 40, 42-44, 49, 51, 53, 60, 68, 69, 71, 72, 81, 83, 90-95, 98, 100, 102, 106, 108, 111, 113, 120, 128, 129, 131, 132, 141, 144, 146, 150, 152, 155, 157, 164, 172, 173, 175, 176, 185 and 187 have been cancelled.

Claims 3, 16-18, 20-25, 32-38, 46, 57-59, 61-67, 73-79, 84, 86-89, 97, 99, 101, 103-105, 107, 109, 110, 112, 114-119, 121-127, 130, 133-140, 142, 143, 145, 147-149, 151, 153, 154, 156, 158-163, 165-171, 177-184, 186, 188, and 189 have been withdrawn.

Claims 1, 190 and 191 have been amended.

Claims 1, 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, 41, 45, 47, 48, 50, 52, 54-56, 67, 70, 80, 82, 85, 190 and 191 are under examination.

 The objection to the disclosure for missing sequence identifiers, preceded by SEQ ID NO is withdrawn in response to Applicant's amendments filed on 09/03/2009.

The provisional rejection of claims 1, 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, 41, 45, 47, 48, 50, 52, 54-56, 67, 70, 80, 82, 85, 190, and 191 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, -9, 12, 14-16, 38-40, and 42 of copending Application No. 10/461,887, in view of both Simmons et al. (Progr. Clin. Biol. Res., 1994, 389: 271-280) and Gerstenfeld et al. (J. Bone Miner. Res., February 2002, 17: 221-230, Abstract) is withdrawn because Applicant submitted a terminal disclaimer on 04/28/2009.

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The rejection of claim 47 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's amendments filed on 09/03/2009.

The rejection of claims 1, 2, 11, and 13-15 under 35 U.S.C. 102(e) as being anticipated by Phillips (U.S. Patent No. 7,282,222), as evidenced by Simmons et al. (Progr. Clin. Biol. Res., 1994, 389: 271-280) is withdrawn in response to Applicant's amendments filed on 09/03/2009.

The rejection of claims 1, 2, 8, 11, 13-15, 29, 39, 45, 52, 54-56, 70, 80, and 190 under 35 U.S.C. 102(e) as being anticipated by Lum et al. (PGPUB 2006/0034767) is withdrawn in response to Applicant's amendments filed on 09/03/2009.

Specification

 The use of the trademarks VYBRANT has been noted in this application (p. 41, lines 8 and 10). It should be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Response to Arguments

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, 41, 45, 47, 48, 50, 52, 54-56, 67, 70, 80, 82, 85, 190, and 191 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Logtenberg et al. (WO 00/23570), in view of each Colsky et al. (J. Immunol. Methods, 1989, 124: 179-187), Kim et al. (J. Immunol. Methods, 1993, 158: 57-65), Caplan et al. (Trends in Molecular Medicine, 2001, 7: 259-264), Thomas et al. (Annals of the Rheumatic Diseases, 1994, 53: 488-496), and Simmons et al (Progr. Clin. Biol. Res., 1994, 389: 271-280).

Logtenberg et al. a method of tissue repair by delivering a cell to a target tissue in a subject, wherein delivery takes place via administration of a composition comprising the cell coated with a targeting moiety, wherein the targeting moiety could be a lipid-modified antibody, and wherein the binding of the targeting moiety to the target tissue selectively directs the cell to the target tissue; Logtenberg et al. also teach that the cells could be genetically modified such as to express IL-2, i.e., the composition comprises a bioactive factors such as an interleukin (claims 1, 8, 13-15, 29, 41, 54-56, 70, 82, and 190) (Abstract, p. 2, lines 24-27, p. 3, lines 23-33, p. 4, lines 1-11 and 29-31, p. 6, lines 1-15, p. 9, lines 4-28, p. 14, lines 8-14, p. 15, lines 19-30).

Although Logtenberg et al. teach coating their cells with lipid-modified antibodies, they do not specifically teach palmitoylated antibodies or attaching the antibody via a palmitoylated protein A linker (claims 4, 6, 9, 47, 48, 50, and 191). However, at the time the invention was made, the use of palmitoylated antibodies or of palmitoylated protein A to coat cells with antibodies was taught by the prior art. For example, Colsky et al.

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teach coating cells with palmitoylated antibodies (Abstract, p. 180, column 1) and Kim et al. teach coating cells with antibodies by using a palmitoylated protein A linker (Abstract, p. 57, column 2, p. 58, column 1, first paragraph). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the composition of Logtenberg et al. by using palmitoylated antibodies or a palmitoylated protein A linker to achieve the predictable result of coating the cells with antibodies.

Although Logtenberg et al., Colsky et al., and Kim et al. teach tissue repair, they do not specifically teach injecting the cell directly into the tissue, wherein the tissue could be cartilage or bone, nor do they teach the cell as being a MSC (claims 2, 39, 45, 80, 85). Caplan et al. teach using MSCs for the tissue repair and the need to specifically target the MSCs to the desired tissue for increased therapeutic efficiency; Caplan et al. also teach that the tissue could be bone or cartilage and that the MSCs could be genetically modified to express bone morphogenic proteins and could be directly injected into the cartilage (p. 261, column 1, p. 262, column 1). Based on these teachings, it would have been obvious to one of skill in the art, at the time the invention was made, to use the method of Logtenberg et al., Colsky et al., and Kim et al. with MSCs to achieve the predictable result of specifically targeting the cells to the damaged cartilage or bone with the purpose of regenerating the damaged cartilage or bone.

Although Logtenberg et al., Colsky et al., Kim et al., and Caplan et al. teach specific delivery to cartilage by using antibody-coated MSCs, they do not specifically teach using anti-collagen II antibodies (claims 26 and 67). However, it is noted that the prior art teaches that collagen II is a cartilage-specific collagen (see Thomas et al., p.

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488, column 1). Therefore, it would have been obvious to one of skill in the art, at the time the invention was made, to use an anti-collagen II antibody in the method of Logtenberg et al., Colsky et al., Kim et al., and Caplan et al. to achieve the predictable result of targeting their MSCs to the cartilage tissue.

With respect to the limitation of Stro-1 as a marker (claims 11 and 52), it is noted that the art teaches that MSCs express Stro-1 (see Simmons et al., p. 273).

Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

Applicant traversed the instant rejection on the grounds that claim 1 is patentable because none of the references cited in the Office Action, alone or in combination, teach a composition including a targeting moiety linked to a progenitor cell in order to target the progenitor cell to a target tissue at a tissue injury site. As discussed in the Office Action, Logtenberg et al. describe anchoring lipid-modified protein to the cellular membrane of target cells useful in targeting specific cells in the body. However, Logtenberg et al. does not teach or suggest linking a targeting moiety (e.g., an antibody) to progenitor cells to target the progenitor cells to a target tissue at a tissue injury site. The Colsky reference describes attaching palmitated antibody onto the surface of macrophages, where the cells serve as surrogate receptors for antigen and to facilitate intercellular interaction. The Colsky reference does not teach or suggest attaching a targeting moiety onto the surface of a cell to enhance adherence of the cell to tissue in which the cells are administered to, let alone linking a targeting moiety to a progenitor

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cell to target the progenitor cell to target tissue at a target tissue injury site.

The Kim reference teaches pal-protein A incorporated onto T-cell hybridoma surfaces which are used to coat cells with antibodies which function as artificial receptors for antigens and to facilitate intercellular interaction. The Kim reference, however, does not teach or suggest attaching a targeting moiety onto the surface of a cell to enhance adherence of the cell to tissue in which the cells are administered to. The Kim reference also fails to teach or suggest linking or attaching a targeting mojety to a progenitor cell to target the progenitor cell to target tissue to enhance adherence of the progenitor cell to the target tissue at a target tissue injury site. Caplan et al. merely discuss the need to increase the efficiency of mesenchymal stem cell engraftment and targeting infused cells to specific tissue locations. Caplan et al. do not teach or suggest a means for increasing the efficiency of mesenchymal stem cell engraftment. Additionally, Caplan et al. fail to teach or suggest targeting infused cells to specific tissue locations. Caplan et al. also fail to teach or suggest a composition having a progenitor cell linked to a targeting moiety capable of targeting target tissue at a target tissue injury site. In addition, Thomas et al. and Simmons et al. fail to make up for the deficiencies of Legtenberg et al., Colsky et al., Kim et al., and Caplan et al. in regard to claim 1. Neither Thomas et al. nor Simmons et al. teach or suggest targeting infused cells to specific tissue locations or a composition having a progenitor cell linked to a targeting moiety capable of targeting target tissue at a target tissue injury site.

Claim 1 is also patentable over the cited references because the Office Action fails to provide a reasonable rationale for combining the teachings of Logtenberg et al.,

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Colsky et al., Kim et al., Caplan et al., Thomas et al., and Simmons et al. More specifically, the references cited in the Office Action do not teach or suggest to the skilled artisan that linking a targeting moiety to a progenitor cell in order to target the progenitor cell to a target tissue at a tissue injury site would be successful. As discussed above, nowhere in the cited references does it teach that one could produce a composition including a targeting moiety linked to a progenitor cell in order to target the progenitor cell to a target tissue at a tissue injury site. For instance, Colsky et al. teach macrophages and mature B cells decorated with palmitate-derivatized antibody. Kim et al. describe T hybridoma cells coated with antibody in order to target surface IgG positive B cells. The references cited in the Office Action do not teach that progenitor cells can be linked to a targeting moiety. As stated above, although Caplan et al. teach the use of mesenchymal stem cells, Caplan et al. merely discuss the need to increase the efficiency of mesenchymal stem cell engraftment and targeting infused cells to specific tissue locations. Caplan et al. do not teach or suggest a means for increasing the efficiency of mesenchymal stem cell engraftment. Thus, the Office Action has failed to provide a reasonable rationale for combining the teaching of Logtenberg et al., Colsky et al., Kim et al., Caplan et al., Thomas et al., and Simmons et al. Applicant submits that the hindsight required to reconstruct the claimed invention from the cited references runs directly contrary to the admonition against hindsight as set out in Graham v. John Deere, an admonition validated by the court in KSR (82 USPQ2d 1385 (2007)) in its insistence that Graham establishes the proper analysis for determination of issue of non-obviousness. More particularly, the rejection is based on the Examiner's

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inference of knowledge which those skilled in the art did not possess at the time the instant invention was made, and this inference has been drawn from disclosure in the instant patent application. For example, there is no evidence that those skilled in the art were aware that it was possible to target tissue at a tissue injury site with a progenitor cell linked to a targeting moiety where the targeting moiety is modified with a lipophilic moiety or the progenitor cell is pre-coated with a linker. Claims 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, and 41 depend either directly or indirectly from claim 1 and are allowable because of the reasons set forth above related to claim 1 and because of the limitations recited in claims 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, and 41.

Claim 190 was also rejected under U.S.C. 103(a) as being unpatentable over Logtenberg et al., in view of Colsky et al., Kim et al. Caplan et al., Thomas et al., and Simmons et al. Claim 190 is patentable for at least the same reasons as stated above in reference to claim 1 and because of the additional limitations of claim 190. Claim 190 recites a method of delivering a progenitor cell to a target tissue in a subject. The method includes coating the progenitor cell with a targeting moiety modified with a lipophilic moiety or the progenitor cell is pre-coated with a linker that binds to a target tissue and the progenitor cell and administering it to a subject in order to enhance adherence of the progenitor cell to the target tissue when administered to a target tissue injury site. As stated above in regards to the rejection of claim 1, Logtenberg et al., in view of Colsky et al., Kim et al., Caplan et al., Thomas et al., and Simmons et al. fail to teach a composition including an targeting moiety linked to a progenitor cell in order to target the progenitor cell to a target tissue at a tissue injury site. In addition, the cited

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references fail to teach or suggest a method of delivering a progenitor cell to a target tissue in a subject including administering a targeting moiety linked to a progenitor cell wherein the targeting moiety is modified with a lipophilic moiety or said progenitor cell is pre-coated with a linker. Therefore, Logtenberg et al., in view of Colsky et al., Kim et al. Caplan et al., Thomas et al., and Simmons et al. do not teach or suggest a composition including a targeting moiety linked to a progenitor cell in order to target the progenitor cell to a target tissue at a tissue injury site. Claims 45, 47, 48, 50, 52, 54-56, 70, 80, 82, 85, and 191 depend either directly or indirectly from claim 190 and are allowable because of the reasons set forth above related to claim 190 and for the limitations recited in claims 45, 47, 48, 50, 52, 54-56, 70, 80, 82, 85, and 191.

Therefore, Applicant requests the withdrawal of the rejection.

Applicant's arguments are acknowledged; however, the rejection is maintained for the following reasons:

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). None of the references has to teach each and every claim limitation. If they did, this would have been anticipation and not an obviousness-type rejection. Therefore, none of the arguments is found persuasive because none addresses the combination of references on which the instant rejection is based.

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In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant argues that there is no evidence that those skilled in the art were aware that it was possible to target tissue at a tissue injury site with a progenitor cell linked to a targeting moiety where the targeting moiety is modified with a lipophilic moiety or the progenitor cell is pre-coated with a linker. This is not found persuasive. It would have been within the knowledge and capabilities of one of skill in the art to extrapolate the teachings of Logtenberg et al. to progenitor cells and further either replacing the lipid of Logtenberg et al. with palmytoyl or attaching the antibody via a palmitoylated protein A linker. Apart from an argument, Applicant did not provide any evidence that one of skill in the art would not have been motivated and would not have been successful in doing such. For the same reasons, Applicant's arguments that, since the cited references do not teach or suggest that linking a targeting moiety to a progenitor cell would be successful, the Office Action fails to provide a reasonable rationale for combining the teachings of cited prior art is not found persuasive.

New Rejections

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Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 2, 4, 6, 8, 9, 11, 13-15, 26, 29, 39, 41, 45, 47, 48, 50, 52, 54-56, 67, 70, 80, 82, 85, 190, and 191 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 12/446,836. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a composition for targeting a progenitor cell to a target tissue, wherein the progenitor cell is modified with a targeting ligand which is linked to the cell either directly or indirectly via a spacer.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

8. Applicant's filing of the new Application No. 12/446,836 on 4/23/2009, i.e., after the mailing date of the non-final Office action (i.e., 10/28/2008) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/ Primary Examiner, Art Unit 1633